1 NAME OF THE MEDICINAL PRODUCT

Ilevro 0.3% Eye Drops, Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active: 1 mL of suspension contains 3 mg nepafenac.
Preservative: benzalkonium chloride 0.005%

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, suspension
Light yellow to dark orange uniform suspension, pH 6.8 (approximately).

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Nepafenac Eye Drops, Suspension 0.3% is indicated in adults for:

- Prevention and treatment of postoperative pain and inflammation associated with cataract surgery
- Reduction in risk of postoperative macular edema associated with cataract surgery in non-proliferative diabetic retinopathy patients.

4.2 Posology and Method of Administration

Posology

Recommended Dose and Dosage Adjustment

For prevention and treatment of postoperative pain and inflammation associated with cataract surgery:

- 1 drop applied to the conjunctival sac of the affected eye(s) once a day beginning 1 day prior to cataract surgery and continuing on the day of surgery and for the first 2 weeks (14 days) of the postoperative period.
- An additional drop should be administered 30 to 120 minutes prior to surgery.
- Treatment can be extended to the first 3 weeks (21 days) of the postoperative period as directed by the clinician.

For reduction in the risk of macular edema associated with cataract surgery in nonproliferative diabetic retinopathy patients:

- The dose of Ilevro is 1 drop in the conjunctival sac of the affected eye(s) once (1) time daily. Dosing begins 1 day prior to surgery, continues on the day of surgery and up to 60 days of the postoperative period, as directed by the clinician.
- An additional drop should be administered 30 to 120 minutes prior to surgery.

Pediatric patients

- The safety and effectiveness of nepafenac in pediatric patients have not been established.
- Its use is not recommended in these patients until further data become available.

Use in hepatic and renal impairment

- Nepafenac has not been studied in patients with hepatic disease or renal impairment.
- No dose adjustment is warranted in these patients, as the systemic exposure is very low following topical ocular administration.

Geriatric population

- No overall differences in safety and effectiveness have been observed between elderly and younger patients.

Method of administration

- For ocular use.
- After cap is removed, if tamper evident snap collar is loose, remove before using product.
- If more than one topical ophthalmic medicinal product is being used, the medicinal products must be administered at least 5 minutes apart. Eye ointments should be administered last.
- If a dose is missed, a single drop should be applied as soon as possible before reverting to regular routine. Do not use a double dose to make up for the 1 missed.
- Shake the bottle well before use.
- To prevent contamination of the dropper tip and solutions, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip of the bottle. Instruct patients to keep the bottle tightly closed when not in use.

4.3 Contraindications

- Hypersensitivity to the active substance, to any of the excipients, or to other non-steroidal anti-inflammatory drugs (NSAIDs).
- Patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or other NSAIDs.

4.4 Special Warnings and Precautions for Use

- Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of Ilevro and should be monitored closely for corneal health.
- Topical NSAIDs may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems. Therefore it is recommended that caution should be exercised if Ilevro is administered concomitantly with corticosteroids, particularly in patients at high risk for corneal adverse reactions described below.
- Post-marketing experience with topical NSAIDs suggests that patients with repeat and/or complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases, dry eye or rheumatoid arthritis may be at increased risk for corneal adverse reactions which may become sight threatening. Topical NSAIDs should be used with caution in these patients. Prolonged use of topical NSAIDs may increase patient risk for occurrence and severity of corneal adverse reactions.
- There have been reports that ophthalmic NSAIDs may cause increased bleeding of ocular tissues (including hyphaemas) in conjunction with ocular surgery. Ilevro should be used with caution in patients with known bleeding tendencies or who are receiving other medicinal products which may prolong bleeding time.

- Ilevro contains benzalkonium chloride which may cause eye irritation and is known to discolor soft contact lenses. Patients should be advised not to wear contact lenses during treatment with Ilevro.
- Benzalkonium chloride has been reported to cause punctate keratopathy and/or toxic ulcerative keratopathy. Close monitoring is required with frequent and/or prolonged use.
- There is a potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other non-steroidal anti-inflammatory agents.
- An acute ocular infection may be masked by the topical use anti-inflammatory medicinal products. NSAIDs do not have any anti-microbial properties. In case of ocular infection, their use with antiinfectives should be undertaken with care.

4.5 Interaction with other Medicinal Products and Other Forms of Interaction

Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems. Concomitant use of Ilevro with medications that prolong bleeding time may increase the risk of hemorrhage.

There are very limited data on the concomitant use of prostaglandin analogues and Ilevro. Considering their mechanism of action, the concomitant use of these medicinal products is not recommended.

4.6 Pregnancy and Lactation

Fertility

There are no adequate data regarding the use of Ilevro on human fertility. No significant fertility effects were seen in studies in rats at doses up to 2500 times greater than the maximum recommended human ocular dose.

Ilevro should not be used by women of child bearing potential not using contraception.

Pregnancy

There are no adequate data regarding the use of Ilevro on human pregnancy. No significant teratogenic effects were observed in rats and rabbits orally administered with doses of nepafenac up to 2500 times greater than the maximum recommended human ocular dose. Since human systemic exposure is negligible (< 1ng/mL) after treatment with Ilevro, the risk during pregnancy could be considered low. Nevertheless, inhibition of prostaglandin synthesis may negatively affect pregnancy and/or embryonal/foetal development and/or parturition and/or postnatal development.

Ilevro is not recommended during pregnancy unless the benefit outweighs the potential risk.

Breast-feeding

It is unknown whether nepafenac is excreted in human milk after topical ocular administration. Animal studies have shown excretion of nepafenac in the milk of rats after oral administration. While no effects on the suckling child are anticipated since the systemic exposure of the breastfeeding woman to nepafenac is negligible (<1 ng/mL), caution should be exercised when Ilevro is administered to a nursing woman.

4.7 Effects on Ability to Drive and Use Machines

Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at application, the patient must wait until the vision clears before driving or using machinery.

4.8 Undesirable Effects

4.8.1 Tabulated list of adverse reactions [Clinical Studies]

The following adverse reactions have been reported during clinical trials with Ilevro and are classified according to the subsequent convention: very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000) and very rare (<1/10,000). Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness.

System Organ Classification	**Adverse reactions [MedDRA Term (version 18.0)]**
Nervous system disorders	*Rare*: dizziness, headache
Eye disorders	*Uncommon*: keratitis, punctate keratitis, corneal epithelium defect, conjunctivitis allergic, eye pain, foreign body sensation in eyes, eyelid margin crusting *Rare*: blurred vision, photophobia, dry eye, blepharitis, eye irritation, eye pruritus, eye discharge, lacrimation increased
Immune system disorders	*Rare:* hypersensitivity
Gastrointestinal disorders	*Rare:* nausea
Skin and subcutaneous tissue disorders	*Rare:* dermatitis allergic

Patients with evidence of corneal epithelial breakdown including corneal perforation should immediately discontinue use of Ilevro and should be monitored closely for corneal health.

Tabulated list of adverse reactions [Post-Marketing Surveillance]

Post marketing experience with topical NSAIDs suggest that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse reaction which may become sight threatening.

Additional adverse reactions identified from post-marketing surveillance include the following. Frequencies cannot be estimated from the available data. Within each System Organ Class adverse reactions are presented in order of decreasing seriousness.

System Organ Classification	**Adverse reactions MedDRA Preferred Term (v. 18.0)**
Eye disorders	corneal perforation, ulcerative keratitis, corneal thinning, corneal opacity, corneal scar, impaired healing (cornea), visual acuity reduced, eye swelling, ocular hyperaemia
Gastrointestinal disorders	vomiting
Investigations	blood pressure increased

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:
Pusat Farmakovigilans/MESO Nasional
Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Badan Pengawas Obat dan Makanan
Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
Email: pv-center@pom.go.id
Phone: +62-21-4244691 Ext.1079
Website: https://e-meso.pom.go.id/ADR
or
Novartis Indonesia
Website: www.novartis.com/report

4.9 Overdose
No toxic effects are likely to occur in case of overdose with ocular use, nor in the event of accidental oral ingestion.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic Properties
Pharmacotherapeutic group: Anti-inflammatory agents, non-steroids, ATC code: S01BC10

Mechanism of action

Nepafenac is a non-steroidal anti-inflammatory and analgesic pro-drug. After topical ocular dosing, nepafenac penetrates the cornea and is converted by ocular hydrolases to amfenac, a non-steroidal anti-inflammatory drug. Amfenac inhibits the action of prostaglandin H synthase (cyclooxygenase), an enzyme required for prostaglandin production.

Pharmacodynamic effects

The majority of hydrolytic conversion is in the retina/choroid followed by the iris/ciliary body and cornea, consistent with the degree of vascularized tissue. No significant effect on intraocular pressure has been reported in clinical trials (Section 4.8).

Clinical Effects

In clinical studies conducted with Nepafenac 3 mg/ mL Eye Drops, Suspension, efficacy for prevention and treatment of postoperative pain and inflammation, was demonstrated in patients undergoing cataract surgery and for reducing the risk of postoperative macular edema was demonstrated in patients with diabetes undergoing cataract surgery.

Pediatric population

Nepafenac has not been studied in pediatric populations.

5.2 Pharmacokinetic Properties
Absorption

For nepafenac 0.3% suspension, once daily dosing in both eyes after four days produced C_{max} of 0.847 ng/mL for nepafenac and 1.13ng/mL for amfenac which was attained at 0.5 hours. The half-life for amfenac was approximately 5-fold longer in plasma than for nepafenac. The steady-state/single dose

mean accumulation ratio was ≈ 1; therefore, no accumulation was observed for either nepafenac or amfenac after ocular dosing with nepafenac 0.3% suspension.

Distribution

Nepafenac and amfenac distributed to ocular tissues in rabbits after single topical dose with either 0.1% or 0.3% suspension. Higher concentrations were observed at site of dosing, cornea and conjunctiva and lower concentrations in posterior tissues, retina and choroid. Concentrations in ocular tissues increased with increased dose. When anterior ocular tissues concentrations were compared from a single dose of 0.3% nepafenac to that after three doses of 0.1% nepafenac in a single day, only the lens did not have a higher concentrations after the 0.3% nepafenac once a day dosing.

In cataract surgical patients, maximal aqueous humor concentrations were observed 1 hour following single dose of 0.1% nepafenac with a concentration of 177 ng/mL and 44.8 ng/mL for nepafenac and amfenac, respectively.

Plasma protein binding of nepafenac is moderate, ranging from 72.8% in rat plasma to 83.5% in human plasma. Protein binding was found to be concentration independent in rat, monkey and human plasma over a wide concentration range (10 to 1000 ng/mL). Amfenac is more highly bound at approximately 99%.

Biotransformation

Nepafenac undergoes relatively rapid *in vivo* hydrolysis to amfenac. After oral administration, unconjugated amfenace and nepafenac, and eight other metabolites were detected in plasma with amfenac, a pharmacological active metabolite having the highest concentration. Several of the metabolites were glucuronide conjugates based chromatographic shift after β-glucuronidase treatment. Nepafenac was detected in plasma but at relatively low levels (3.2% of total radioactivity). Amfenac was the major metabolite in plasma, representing approximately 13% of total plasma radioactivity. The second most abundant plasma metabolite was 5-hydroxy nepafenac in the form of a glucuronide, representing approximately 9.5% of total radioactivity at C_{max}.

Neither nepafenac nor amfenac inhibit any of the major human cytochrome P-450 isozymes (CYP1A2, 2C9, 2C19, 2D6, 2E1 and 3A4) *in vitro* at concentrations up to 3000 and 1000 ng/mL, respectively.

After 14 days of oral administration, nepafenac does not increase CYP1A, CYP2B, CYP3A activities or total P450 content in rat, therefore no potential induction was observed for rat.

Elimination

After oral administration of ^{14}C-nepafenac to healthy human volunteers, urinary excretion was found to be the major route of excreted radioactivity, accounting for approximately 85% while fecal represented approximately 6% of the dose out to 7 days.

5.3 Preclinical Safety Data

Non-clinical data reveal no special hazard for humans based upon conventional studies of safety Pharmacology, repeated dose toxicity or genotoxicity. Nepafenac has not been evaluated in long-term carcinogenicity studies.

Fertility and developmental and reproductive toxicity effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Carmellose sodium (carboxymethylcellulose sodium)
Guar
Carbomer 974P
Boric acid
Disodium edetate
Propylene glycol
Sodium chloride
Benzalkonium chloride
Sodium hydroxide and/or hydrochloric acid (for pH adjustment)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

The expiry date is indicated in the outer packaging

6.4 Special Precautions for Storage

Store in a refrigerator (2°C to 8°C)
After first opening: Store at not more than 30°C (up to 30 days). Protect from light.
Discard 4 weeks after first opening

6.5 Nature and Contents of Container

4 mL round or oval low density polyethylene bottle with a dispensing plug and white polypropylene screw cap containing 3 mL suspension. The bottle may be presented in a pouch.
Carton containing 1 bottle.

6.6 Instructions for Use and Handling

No special requirements.

HARUS DENGAN RESEP DOKTER

PACKAGING: Box, 1 Plastic bottle @ 3 mL
Reg. No.

Manufactured by Novartis Manufacturing NV, Puurs-Sint-Amands, Belgium
Imported by PT Novartis Indonesia, Jakarta, Indonesia

Leaflet based on TDOC-0051366v2.0, Removal Droptainer, and PUURS LENC

Informasi Produk untuk Pasien
ILEVRO®
Nepafenac 3 mg/mL, suspensi tetes mata

Mohon brosur dibaca dengan seksama sebelum Anda memakai obat ini
Mohon agar brosur ini disimpan. Anda mungkin akan membutuhkan brosur ini untuk dibaca kembali.
Jika Anda ingin bertanya lebih lanjut, mohon hubungi dokter atau apoteker Anda.
Obat ini diresepkan untuk Anda. Mohon jangan berikan obat ini kepada orang lain meskipun mereka memiliki gejala penyakit yang serupa dengan Anda.
Jika Anda mengalami efek samping yang berat, atau jika Anda mengalami efek samping yang tidak tertera pada brosur ini, mohon informasikan kepada dokter ataupun apoteker Anda.

Daftar Isi

1. Apakah Ilevro dan apa kegunaannya

Apakah Ilevro
Ilevro merupakan suspensi tetes mata yang mengandung zat aktif nepafenac 3 mg/mL.

Apakah kegunaan Ilevro
Ilevro digunakan untuk:
- Pencegahan dan pengobatan rasa sakit paska operasi dan peradangan yang berhubungan dengan operasi katarak.
- Mengurangi resiko edema makula paska operasi yang berhubungan dengan operasi katarak pada pasien Retinopati Diabetika Non Proliferatif.

Ilevro mengandung zat aktif nepafenac. Zat aktif ini termasuk ke dalam golongan obat-obatan anti inflamasi non steroid (*Non-steroidal anti-inflammatory drugs*/NSAIDs).
Golangan obat-obatan ini menghilangkan rasa sakit dan mengurangi peradangan (misalnya pembengkakan, kemerahan dan berdenyut).
Dokter Anda bisa saja meresepkan Ilevro untuk kegunaan lain. Tanyakan kepada dokter jika Anda memiliki pertanyaan mengapa Anda diresepkan Ilevro.
Tidak ada bukti bahwa Ilevro menimbulkan ketergantungan.

Penggunaan pada Anak-anak
Tetes mata Ilevro tidak direkomendasikan pada anak dan remaja di bawah usia 18 tahun dikarenakan belum ada bukti keamanan dan kemanfaatan pada anak-anak.

2. Apa yang harus diketahui sebelum dan ketika menggunakan Ilevro

Jangan menggunakan Ilevro jika:
Anda memiliki alergi (hipersensitif) terhadap nepafenac, atau bahan tambahan lain yang terkandung dalam obat ini atau Anda memiliki alergi terhadap obat-obatan anti inflamasi non-steroid (NSAIDs). Jika Anda pernah mengalami asma, alergi kulit, atau radang serius di hidung Anda saat menggunakan NSAID lain. Contoh NSAID adalah: asam asetilsalisilat, ibuprofen, ketoprofen, piroxicam, dan diklofenak.

Berikan perhatian khusus pada saat menggunakan Ilevro jika:
- Anda mudah mengalami memar atau memiliki masalah perdarahan atau sedang menggunakan obat-obatan yang dapat memperpanjang waktu perdarahan.
- Anda mengalami gangguan mata (misalnya mata kering, luka pada kornea atau gangguan epitel).
- Anda memiliki penyakit sistemis seperti diabetes dan *rheumatoid arthritis*.
- Anda mengalami operasi mata berulang atau operasi mata dengan komplikasi
- Anda menggunakan lensa kontak
- Anda sedang menggunakan steroid atau obat anti inflamasi non-steroid topikal lainnya karena ini dapat memperlambat atau menunda penyembuhan luka mata Anda.

Beritahukan kepada dokter Anda jika kondisi di atas terjadi pada Anda. Anda mungkin masih dapat menggunakan Ilevro, tetapi diskusikan dahulu dengan dokter Anda sebelum menggunakan Ilevro.

Menggunakan obat lainnya
Beritahukan kepada dokter atau Apoteker Anda jika anda sedang atau baru saja menggunakan obat-obatan lainnya, termasuk obat yang bisa Anda dapatkan tanpa resep dokter. Ilevro dapat mempengaruhi atau dipengaruhi oleh obat-obatan lain yang Anda gunakan, termasuk obat tetes mata yang digunakan untuk pengobatan glaukoma.

Terutama, beritahukan kepada dokter Anda jika Anda sedang menggunakan NSAID topikal. Penggunaan bersamaan dengan steroid topikal dan NSAID topikal dapat meningkatkan masalah pada penyembuhan mata. Juga beri tahu dokter Anda jika Anda meminum obat yang mengurangi pembekuan darah (warfarin) atau NSAID lainnya. Obat tersebut dapat meningkatkan risiko pendarahan.

Penggunaan selama kehamilan dan menyusui
Jika Anda hamil, atau berpotensi hamil, bicarakan dengan dokter Anda sebelum menggunakan Ilevro. Ilevro tidak direkomendasikan selama kehamilan.

Jika Anda sedang menyusui, Ilevro dapat dialirkan ke Air Susu Ibu. Meskipun tidak ada efek yang diantisipasi untuk bayi yang menyusui, Ilevro harus digunakan dengan hati-hati selama menyusui. Konsultasikan dengan dokter Anda sebelum menggunakan Ilevro.

Mengemudi dan mengoperasikan mesin
Penglihatan Anda mungkin menjadi buram sesaat setelah penggunaan Ilevro. Jangan mengemudi atau mengoperasikan mesin sampai penglihatan Anda kembali jernih.

Informasi penting mengenai beberapa zat tambahan dalam Ilevro mengandung benzalkonium klorida:

- Ilevro menggunakan zat pengawet benzalkonium klorida yang dapat menyebabkan perubahan warna pada *soft lenses* dan menyebabkan iritasi mata. Selain itu, penggunaan lensa kontak juga tidak dianjurkan setelah operasi katarak. Oleh karenanya, jangan menggunakan lensa kontak saat sedang menggunakan Ilevro.

3. Bagaimana cara menggunakan Ilevro
Dosis yang direkomendasikan:
Untuk pencegahan dan pengobatan rasa sakit paska operasi dan peradangan yang berhubungan dengan operasi katarak.:

- 1 tetes pada kantung konjungtiva pada mata yang sakit satu kali sehari dimulai sejak 1 hari sebelum operasi katarak dan dilanjutkan pada hari saat Anda menerima operasi dan selama 2 minggu (14 hari) setelah operasi katarak.
- Tetes tambahan harus diberikan dalam jangka waktu 30 sampai 120 menit sebelum operasi.
- Pengobatan dapat diperpanjang sampai 3 minggu (21 hari) pertama setelah operasi katarak sesuai petunjuk dokter.

Untuk mengurangi resiko edema makula paska operasi yang berhubungan dengan operasi katarak pada pasien Retinopati Diabetika Non Proliferatif

- 1 tetes pada kantung konjungtiva pada mata yang sakit satu kali sehari. Dosis dimulai sejak 1 hari sebelum operasi dan dilanjutkan pada hari saat Anda menerima operasi hingga 60 hari setelah operasi, sesuai petunjuk dokter.
- Tetes tambahan harus diberikan dalam jangka waktu 30 sampai 120 menit sebelum operasi.

Selalu gunakan Ilevro sesuai dengan petunjuk dokter Anda. Anda harus mengecek kepada dokter atau Apoteker Anda jika Anda tidak yakin.
Selalu gunakan Ilevro sebagai tetes mata.
Sebelum tutup dibuka, lepaskan segel pengaman di sekitar leher botol dan buang plastiknya.
Jika ada tetesannya tidak masuk ke mata Anda, coba lagi.

Jika Anda menggunakan Ilevro lebih dari yang seharusnya, bilas mata Anda dengan air hangat. Jangan menambahkan tetesan sampai jadwal pemberian selanjutnya.

Jika Anda lupa menggunakan Ilevro, segera berikan dosis tunggal segera setelah Anda ingat. Jika sudah mendekati jadwal penggunaan selanjutnya, lewati dosis yang terlupa/terlewat dan lanjutkan pada jadwal yang normal. Jangan menggunakan dosis ganda untuk menutup dosis yang Anda lewatkan**.**

Jika Anda sedang menggunakan tetes mata lain, tunggu sekitar lima menit antara penggunaan Ilevro dan tetes mata lainnya.

Untuk mencegah kontaminasi dari ujung botol (*dropper tip*) dan larutan tetes mata, perlu diperhatikan agar tidak menyentuh kelopak mata, area sekitar atau permukaan lain dengan ujung botol. Simpan botol dalam kondisi tertutup rapat jika tidak sedang digunakan.

Jika Anda memiliki pertanyaan lebih lanjut terkait penggunaan obat ini, tanyakan kepada dokter atau Apoteker Anda.

4. Efek samping yang mungkin terjadi

Seperti obat-obatan lainnya, Ilevero dapat menyebabkan efek samping, meskipun tidak semua orang mengalaminya.

Beberapa efek samping di bawah ini telah diobservasi selama penggunaan Ilevro:

Efek samping tidak umum *(dapat mempengaruhi sampai 1 dari 100 orang)*

- **Efek pada mata:** inflamasi permukaan mata, *allergic conjunctivitis* (alergi pada mata), nyeri pada mata, sensasi asing pada mata, pengerasan kelopak mata (*eyelid crusting*).

Efek samping yang jarang *(dapat mempengaruhi sampai 1 dari 1.000 orang)*

- **Efek pada mata:** penglihatan buram, sensitif terhadap cahaya, mata kering, pembengkakan kelopak mata, iritasi mata, mata gatal, *eye discharge* dan peningkatan produksi air mata.
- **Efek samping umum:** pusing, alergi kulit, sakit kepala,mual dan hipersensitifitas.

Efek samping dengan frekuensi tidak diketahui (tidak dapat diestimasi dari data yang tersedia)

- **Efek pada mata**: kerusakan pada area sekitar mata seperti penipisan atau perforasi, inflamasi mata, *clouding*, luka pada permukaan mata, gangguan penyembuhan mata, visi berkurang, pembengkakan mata dan mata merah.
- **Efek samping umum:** muntah dan peningkatan tekanan darah.

Anda mungkin memiliki efek samping terhadap kornea (permukaan mata) yang lebih tinggi jika Anda memiliki:

- Operasi mata dengan komplikasi
- Operasi mata berulang dalam waktu singkat
- Gangguan tertentu pada permukaan mata, seperti peradangan atau mata kering
- Penyakit umum tertentu, seperti diabetes atau rheumatoid arthritis.

Pelaporan efek samping

Apabila ada keluhan efek samping atau kondisi tidak nyaman selama dan setelah penggunaan obat, konsultasikan ke dokter, apoteker, atau perawat. Anda dapat juga melaporkan keluhan efek samping atau kondisi tidak nyaman tersebut secara langsung ke Industri Farmasi melalui kontak berikut:

Novartis Indonesia

Website: www.novartis.com/report

Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut mengenai keamanan obat ini.

5. Cara penyimpanan Ilevro

- Simpan di lemari es (suhu 2°C - 8°C)
- Setelah dibuka: simpan pada suhu tidak lebih dari 30°C (maksimal selama 30 hari). Lindungi dari cahaya.
- Jangan dipakai setelah tanggal kadaluarsa yang tercantum pada kemasan.
- Jauhkan dari penglihatan dan jangkauan anak-anak.
- Jangan dipakai setelah 4 minggu sejak pertama kali dibuka.

6. Isi dari kemasan dan informasi lain

Apakah isi dari Ilevro

Zat aktif dari Ilevro adalah nepafenac.

Kandungan lain (zat tambahan) yang digunakan pada Ilevro adalah *carmellose sodium (carboxymethylcellulose sodium), guar, Carbomer 974P,* asam borat, *disodium edetate,* propilen glikol, natrium klorida, benzalkonium klorida, natrium hidroksida dan/atau asam hidroklorat (untuk menyesuaikan pH), *purified water*.

Bagaimana bentuk Ilevro dan isi kemasannya

Ilevro merupakan suspensi tetes mata seragam berwarna kuning terang sampai oranye tua/gelap dengan pH sekitar 6.8.

Kemasan Ilevro berupa botol *low density polyethylene* ukuran 4 mL berbentuk bulat atau oval dengan penutup (*dispensing plug*) dan tutup polypropylene putih dan mengandung suspensi sebanyak 3 mL.

Kemasan: Dus, botol plastik @ 3mL

No. Reg.

HARUS DENGAN RESEP DOKTER

Diproduksi oleh Novartis Manufacturing NV, Puurs-Sint-Amands, Belgium

Diimpor oleh PT Novartis Indonesia, Jakarta, Indonesia

PIL based on BPL TDOC-0051888 refer to CCDS TDOC-0051366v2.0, Removal droptainer, and PUURS LENC